



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 301-435-0668

FAX: 301-402-2071

E-mail: pmcneilly@osophs.dhhs.gov

April 15, 2005

Antonio M. Gotto, Jr., M.D., D.Phil.
Provost for Medical Affairs and
Dean of the Medical College
Joan and Sanford I. Weill College of Medicine
of Cornell University
1300 York Avenue, Room F105
New York, NY 10021

Sheila Cohen Zimmet, R.N., J.D.
Associate Dean for Research
Joan and Sanford I. Weill College of Medicine
of Cornell University
1300 York Avenue, Box 5
New York, NY 10021

**RE: Human Research Subject Protections Under Multiple Project Assurance M-1185
and Federalwide Assurance FWA-93**

<u>Research Project:</u>	Cytokines and Extracellular Matrix in Bronchopulmonary Dysplasia (Protocol # 0199-520)
<u>Principal Investigators:</u>	Dr. Zubair Aghai, Dr. Harmut Hanauske-Abel, and Dr. Alfred Krauss
<u>Research Project:</u>	Effects of Diurnal Hormonal Changes on Matrix Metabolism (Protocol # 1296-629)
<u>Principal Investigator:</u>	Dr. Madeleine Harbison
<u>Research Project:</u>	Endocrine Function in Fanconi Anemia (Protocol # 0694-480)
<u>Principal Investigator:</u>	Dr. Michael Wajnrach

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Research Project: **Hypo-Hyperadrenal States (Protocol # 0296-223)**
Principal Investigator: **Dr. Maria New**

Research Project: **A Clinical Trial to Prevent the Complications of Insulin
Resistance (Including Type II Diabetes) (Protocol #
0800-354)**
Principal Investigator: **Dr. Noel Maclaren**

Dear Dr. Gotto and Ms. Cohen Zimmet:

The Office for Human Research Protections (OHRP) has reviewed the Weill Medical College of Cornell University's (WMC) March 31, 2005 report, which was submitted in response to OHRP's January 12, 2005 letter.

After reviewing your report, OHRP notes the following additional corrective actions taken by WMC:

- (1) The informed consent document for Protocol #0702-342 has been revised to contain language that would be understandable to the subjects enrolling.
- (2) The WMC institutional review board (IRB) has terminated Protocol #0403-771 and has determined that no subjects were enrolled at WMC.
- (3) The WMC has provided additional training opportunities to its IRB members, staff, and investigators.

As a result of these corrective actions, as well as those noted in OHRP's letters of July 21, 2004; September 9, 2004; and January 12, 2005, OHRP finds that WMC has adequately addressed the determinations made in OHRP's letter of May 24, 2004. As a result of this determination, effective immediately, OHRP is removing the restriction on the WMC Federalwide Assurance (FWA-93), and WMC no longer needs to submit quarterly progress reports to OHRP. Furthermore, there should be no need for further involvement of OHRP in this matter. However, OHRP anticipates conducting a follow-up site visit to WMC within the next 12-24 months.

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OHRP appreciates WMC's continued commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. Jeffrey Lehman, President, Cornell University
Ms. Dorothy Hilpmann, IRB Administrator, WMC
Dr. David Behrman, Chairperson, IRB WMC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Lana Skirboll, NIH
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borrer, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP